Publications and events

Access to medicines

WHO submission to the UN High-Level Panel
Geneva – WHO has made a submission to the UN Secretary-General’s High-Level Panel on Access to Medicines to recommend solutions to remedy the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies. The submission presents WHO’s experience and a number of ongoing WHO projects to foster the development of priority health products, including the WHO/DNDi Global Antibiotic R&D Partnership, and makes a number of suggestions for possible areas of action to the Panel.

► WHO Submission to the UN SG High Level Panel on Access to Medicines. 17th March 2016.

Regulatory approaches to make medicines more affordable
European Union – In an article published in the New England Journal of Medicine, representatives of European regulatory authorities discuss possible regulatory interventions to facilitate continued access to safe and effective medicines in health systems at affordable prices.

The authors argue that although the pricing of medicines is clearly out of their remit, regulators cannot ignore the current debate on the cost of medicines. They propose five main ways how regulators can make a contribution to affordable health care: 1) Enable the rapid approval of generics and biosimilars; 2) ensure that medicines comparable to already approved ones continue to come on the market, thus increasing competition; 3) encourage clinical trials that demonstrate safety and efficacy and also provide data to guide reimbursement decisions; 4) facilitate the collection of post-approval data that are important for payers, for example data on outcomes for patients; and 5) foster new models for research and development enabling companies to reduce the price of their medicines.

► EMA News, 12 May 2016.

UNAID discussion paper on affordability of essential medicines
Geneva – UNITAID has published a discussion paper that assesses the affordability of medicines and biologicals to treat hepatitis C, cancer and multi drug-resistant tuberculosis and proposes options for making them more affordable through price negotiations, voluntary licensing, patent pooling, and use of TRIPS flexibilities. The report emphasizes that the recent shifts in the WHO Essential Medicines paradigm demand a bold approach to avoid unnecessary delays in
making these medicines available to the populations in need.

► Ensuring that essential medicines are also affordable medicines: challenges and options. Discussion paper. Geneva: WHO (Acting as the host organization for the Secretariat of UNITAID), 2016.

Intellectual property and local medicines production
Geneva – A new WHO study on the role of intellectual property in medicines production sets out strategies and options to facilitate local production in developing countries. Using practical examples and patent landscapes, the report describes the options available to countries with a generic pharmaceutical industry to design an intellectual property system that is favourable for local production and potentially for public health.

The report contains detailed patent information on atazanavir, raltegravir, imatinib, sitagliptin, pegylated interferon alfa-2a, and human papillomavirus vaccine (Gardasil®).


GlaxoSmithKline announces new approach to patents
Ahead of the meeting of the UN High Level Panel on Access to Medicines, GlaxoSmithKline (GSK) has announced its new and more flexible approach to patents and intellectual property to increase access to medicines. The company plans to use a graduated approach to filing and enforcing patents depending on a country's economic maturity, seeking full patent protection only in high income countries, upper middle income countries and G20 countries. Additionally, GSK intends to commit its future portfolio of cancer treatments to patent pooling and will explore the concept with the Medicines Patent Pool (MPP). GSK would be the first company to licence cancer medicines to the patent pool. GSK will also work towards making information about its current and future patent portfolio freely available. (1)

The Union for Affordable Cancer Treatment (UACT) has welcomed the announcement, stating that it is "significant and encouraging" that GSK is seeking collaboration with the MPP, a public health-driven licensing mechanism with a proven track record. (2)

(2) UACT Statement, 6 April 2016.

Study shows hepatitis C medicines prices are globally unaffordable
A comparative study of prices and affordability of sofosbuvir and ledipasvir/sofosbuvir across 30 countries has shown that current prices of these medicines are variable and unaffordable globally. A fairer pricing framework is needed if countries are to increase investment to minimize the burden of hepatitis C.


DNDi and pharmaceutical company to test new hepatitis C medicine
Barcelona – The Drugs for Neglected Diseases initiative (DNDi) and the Egyptian pharmaceutical company Pharco Pharmaceuticals have signed agreements covering the clinical testing
and scale-up of a hepatitis C treatment regimen at a price of just under US$ 300. The announcement was made at the International Liver Congress 2016 in Spain. The regimen consists of a combination of ravidasvir – an NS5A inhibitor – and sofosbuvir. Phase III studies will be conducted in Malaysia and Thailand in patients with various levels of liver fibrosis, various genotypes of hepatitis C virus, and with and without HIV co-infection to compare the new regimen with the combination of sofosbuvir and daclatasvir, a current standard of care.

► DNDi Press release, 13 April 2016.

Medicines patent pool and TB Alliance to collaborate

New York and Geneva – The TB Alliance and the Medicines Patent Pool (MPP) have announced a Memorandum of Understanding to encourage the development of new tuberculosis (TB) regimens and ensure their availability in low-and middle-income countries. The two organizations will work together on licensing strategies for future tuberculosis drug regimens developed by TB Alliance and promoting their uptake in high burden countries. They will also collaborate on identifying promising future anti-tuberculosis compounds for licensing opportunities and on improving access to correctly dosed, properly formulated anti-TB medicines for children. The parties will share information with other public health organizations to develop market forecasts and intelligence.

The agreement comes five months after UNITAID, the organization that funds the MPP, approved its expansion into the new areas of hepatitis C and tuberculosis.


Disease updates

HIV and hepatitis C co-infection

Geneva – A WHO-commissioned study has found that an estimated 2.3 million people globally are co-infected with HIV and hepatitis C virus (HCV). More than half of these are people who inject drugs. HIV-infected people were found to be six times more likely than HIV-uninfected people to have HCV infection.

Globally, there are 37 million people infected with HIV and around 115 million people with chronic HCV infection. The study found that 27% of all HIV/HCV co-infections were in eastern Europe and central Asia, where injecting drug use is driving the co-infection epidemic. The sub-Saharan African region accounted for 19% of all cases due to high burdens of HIV.

This first global study of its kind was sponsored by WHO and conducted in collaboration with the London School of Hygiene & Tropical Medicine and the University of Bristol. It points to the need to improve HCV and HIV surveillance and integrated HIV/HCV services and to scale up preventive interventions and access to HIV and HCV treatment.


Diabetes: global action needed

Geneva – WHO has released its first global report on diabetes, which reveals that the number of people living with this disease has almost quadrupled since 1980. In 2014 an estimated 422 million adults were living with diabetes, most
of them living in developing countries. Diabetes caused 1.5 million deaths in 2012, of which 43% occurred before the age of 70 years. Diabetes has far-reaching health and socioeconomic impacts.

Good management of diabetes includes use of a small set of generic medicines, interventions to promote healthy lifestyles, patient education to facilitate self-care, and regular screening for early detection and treatment of complications. Insulin and oral hypoglycaemic agents are reported as available and affordable in only a minority of low-income countries. Global action is needed to halt the rise in diabetes and obesity, and to make affordable essential medicines available to all people living with diabetes.

► WHO News release, 6 April 2016.

Depression and anxiety: the investment case

The results of a new WHO-led study show that investing in treatment for depression and anxiety leads to fourfold returns in terms of better health and ability to work.

Depression and anxiety disorders cost the global economy US$ 1 trillion each year. Between 1990 and 2013, the number of people suffering from depression and/or anxiety increased by nearly 50%, from 416 million to 615 million or close to one tenth of the world’s population.

Governments spend on average 3% of their health budgets on mental health, ranging from less than 1% in low-income countries to 5% in high-income countries. Scaling up of mental health services is needed to achieve the Sustainable Development Goals target that calls for a reduction by one third, in the next 15 years, of the premature mortality from non-communicable diseases, including through promotion of mental health and well-being.


Multidrug-resistant tuberculosis: WHO recommends shorter regimen

Geneva –WHO has published new recommendations to speed up the detection and improve treatment outcomes for multidrug resistant tuberculosis (MDR-TB) through use of a novel rapid diagnostic test and a shorter, cheaper treatment regimen. At less than US$ 1 000 per patient, the new treatment regimen can be completed in 9–12 months, as opposed to 18–24 months for conventional regimens.

The shorter regimen is recommended for patients diagnosed with uncomplicated MDR-TB, for example those without resistance to fluoroquinolones and injectable second-line drugs, and those who have not yet been treated with second line drugs. A new diagnostic test – called MTBDRsl – gives results on resistance to second-line drugs in just 24–48 hours, down from the 3 months or longer required with other tests. This new test has the potential to support the appropriate use of the shortened treatment regimen and can thus help to accelerate the global MDR-TB response.

► WHO News release, 12 May 2016.
Malaria: push for further progress
Geneva – A WHO report released on the occasion of World Malaria Day shows that the goal to eliminate malaria from at least 35 countries by 2030, adopted a year ago by the World Health Assembly, is ambitious but achievable. Many countries are well on their way towards malaria elimination, and malaria mortality rates have declined by 60% globally since the year 2000. However, nearly half of the world’s population remain at risk of malaria, and there is an urgent need for greater investment in high transmission settings, particularly in Africa.

With growing mosquito resistance to insecticides and parasite resistance to antimalarials, new technologies need to be developed. As countries approach elimination, the ability to detect every infection also becomes increasingly important. Further progress in the fight against malaria will require strong leadership by governments of affected countries and an increase in global and domestic funding from currently $2.5 billion to about $8.7 billion annually by 2030. (1)

Two UNITAID reports published ahead of 2016 World Malaria Day foresee a rising demand for malaria diagnostics and treatment through 2018, despite recent sharp declines in malaria prevalence worldwide. Over 400 million treatments and a vast scale-up in the market for malaria rapid diagnostic tests are needed over the next three years to meet global targets for eliminating malaria. (2)

Zika: WHO identifies research and development priorities
Geneva – International experts convened by WHO have agreed on the research and development (R&D) priorities to protect pregnant women and their infants from the consequences of Zika virus infection. Products to be prioritized include multiplex tests for Zika and other flaviviruses such as dengue and chikungunya in addition to more traditional tests, inactivated Zika vaccines for women of childbearing age, and innovative vector control tools that reduce the mosquito population.

A number of such products are at an early stage of development. WHO will propose target product profiles for vaccines and diagnostics for public consultation. The R&D community has responded vigorously to WHO’s call for applications under the WHO Emergency Use, Assessment and Listing (EUAL) procedure. A major advance compared to the Ebola product R&D response of 2014–2015 is the speed with which data and experiences are being shared.

► WHO Note for the media, 9 March 2016.

Ebola: no longer a public health emergency
Geneva – The 9th meeting of the International Health Regulations (IHR) Emergency Committee has stated that the Ebola situation in West Africa no longer constitutes a Public Health Emergency of International Concern (PHEIC). The WHO Director-General has terminated the PHEIC in accordance with the International Health Regulations (2005) as well as the Temporary Recommendations that she had issued in relation to this event. The crucial need was emphasized for continued international donor and technical support to prevent, detect
and respond rapidly to any new Ebola outbreak in West Africa. *(1)*
In early June WHO declared the end of Ebola virus transmission in the Republic of Guinea *(2)* and in Liberia *(3)*, as 42 days had passed from the second negative test of the last person with confirmed infection.

► *(1)* WHO Statement, 29 March 2016.
 *(2)* WHO AFRO News release, 1st June 2016.

### Vaccination

#### Recent gains and remaining gaps

**Geneva** – During World Immunization Week 2016, held on 24-30 April, WHO has highlighted recent gains in immunization coverage – with polio having eliminated in one country, tetanus in three, and rubella in one geographical region in 2015 – and has outlined further steps that countries can take to meet global vaccination targets by 2020 as defined in the Global Vaccine Action Plan. Immunization averts 2–3 million deaths annually. However, an additional 1.5 million deaths could be averted if global vaccination coverage improves.

Quality and use of data have been identified as factors that can help improve vaccine coverage. In accordance with a 2015 World Health Assembly resolution WHO has collected 1 600 vaccine price reports in what is today the largest international vaccine price database. Prices paid for vaccines represent a large share of countries’ immunization budgets, and cost can represent a barrier preventing countries from introducing new vaccines.

 *(WHO, V3P vaccine price database.)*

### Controlled substances

#### A public health approach to the world drug problem

**New York** – At the United Nations General Assembly Special Session on the World Drug Problem held on 19-21 April in New York, WHO highlighted the public health dimensions of this issue. Psychoactive drug use causes more than 400 000 deaths each year and contributes significantly to epidemics of HIV, viral hepatitis and tuberculosis in all regions of the world. National drug policies often focus on law enforcement, with little attention given to prevention, treatment and harm reduction or access to controlled medicines. It is estimated that 83% of the world’s population live in countries with low or non-existent access to controlled medicines for the management of moderate to severe pain. *(1)*

WHO’s role in promoting a public health-oriented approach to addressing the world drug problem was also discussed by the WHO Executive Board and brought to the attention of the Sixty-ninth World Health Assembly. *(2)*


### WHO matters

#### Sixty-ninth World Health Assembly: setting the course for global public health

**Geneva** – Some 3 500 delegates from WHO’s 194 Member States attended the Sixty-ninth World Health Assembly, held on 23–28 May 2016. In her opening speech, the WHO Director-General
emphasized that universal health coverage will be key to achieving health-related targets of the sustainable development agenda.

The Assembly took a number of decisions related to medical products. It adopted global health sector strategies on HIV, viral hepatitis and sexually transmitted infections for the period 2016–2021, aiming to scale up treatment, use of diagnostics and prevention measures in line with the targets laid down in the Sustainable Development Goals. Delegates further agreed on a range of measures to ensure access to needed medicines and vaccines, to address global shortages (see also page 180), and to identify gaps in health research and development, especially for diseases that disproportionately affect developing countries and attract little investment.

Resolutions were approved on the new WHO health emergencies programme, the International Health Regulations, resilient integrated health services, the Sustainable Development Goals, WHO’s engagement with non-state actors, and a number of other issues.

► WHO News release, 28 May 2016.

New WHO medicines quality guidelines published

Geneva – WHO has published the 50th meeting report of its Expert Committee on Specifications for Pharmaceutical Preparations. The ten annexed guidelines include five new texts on such important issues as good data management practices, good pharmacopoeial practices, conducting medicines quality surveys, and provision by health professionals of children-specific medicines that are not available as authorized products. Revised guidelines were adopted on good manufacturing practices for biologicals (following their adoption by the Expert Committee on Biological Standards a day earlier), good trade and distribution practices for starting materials, and three other topics.

► WHO Essential medicines and health products. WHO Expert Committee on specifications for pharmaceutical preparations (Fiftieth report) [web page].

WHO announces Phase 7 of its external assessment scheme for quality control laboratories

Geneva – WHO has announced Phase 7 of its External Quality Assurance Assessment Scheme (EQAAS). The Scheme was established by WHO in 2000 at the request of the Global Fund as a mechanism to maximize health benefits achieved on grant investments in pharmaceuticals and laboratory supplies. The EQAAS has proven to be a major asset to WHO Member States. More than 60 laboratories across WHO’s six regions have participated in past studies. Participation in comparative external assessment studies is mandatory according to WHO's good practices for pharmaceutical quality control laboratories and for ISO 17025 accreditation.

The WHO EQAAS is at present the only global, independent scheme to measure laboratories’ QC testing capabilities. WHO is pleased to be able once more to offer preferential fees far below cost for participants from low- and middle-income countries. For more information and expression of interest to participate, please contact WHO at EQAAS@who.int.

► Information about EQAAS: WHO Essential medicines and health products. External quality assurance assessment scheme (EQAAS) [web page].
Primaquine invited for prequalification

Geneva – The WHO Prequalification Team has published its 10th Invitation for Expression of Interest (EOI) for prequalification of active pharmaceutical ingredients (API) and its 13th EOI for antimalarial medicines. The two revised EOIs newly include primaquine API and tablet formulations.

► 10th Invitation to manufacturers of Active Pharmaceutical Ingredients (API) to submit an Expression of Interest (EOI) for API evaluation to the WHO Prequalification Team: medicines. 27 April 2016.

► 13th Invitation to manufacturers of antimalarial medicines to submit an Expression of Interest (EOI) for product evaluation to the WHO Prequalification Team - Medicines (April 2016).

Prequalification of vector control products

Geneva – WHO has launched a new temporary website for the prequalification of vector control products. Review functions for these products, previously carried out by the Control of Neglected Tropical Diseases department, have been transferred to the WHO Prequalification Team (PQT). This reflects part of WHO’s evolving approach to supporting the development, evaluation and adoption of new vector control products and tools.

PQT’s quality assurance processes, together with its close engagement with regulatory authorities globally, build on WHO’s work to ensure that vector control products and pesticidal active ingredients (for public health purposes) are effective, safe, and meet stringent quality and manufacturing standards. Key steps of the prequalification process include assessment of product dossiers, inspection of manufacturing sites, and supporting quality control testing of products. Finally, products and manufacturing sites that meet prequalification requirements are added to (a) the WHO list of vector control products or (b) the WHO list of manufacturing sites for public health pesticidal active ingredients, respectively.

Current vector control interventions face serious challenges, including increasing insecticide resistance, rapidly expanding arboviral diseases and the impact of climate change on vector distributions. To respond to these challenges, there is an urgent demand for innovative vector control products and the development of new tools and approaches.

► WHO Prequalification Team: vector control products (WHO PQ update, 7 June 2016).
Upcoming events

17th ICDRA
Registration is now open for the 17th International Conference of Drug Regulatory Authorities (ICDRA), which will be held at the International Convention Centre (ICC) in Cape Town, South Africa, on 29 November–2 December 2016. A pre-ICDRA conference event titled “Patients are Waiting: How Regulators Collectively Make a Difference” will be convened on 27–28 November 2016 at the same venue.

The 17th ICDRA will facilitate focused discussions on medicines regulatory harmonization, strengthening of regulatory systems, regulatory preparedness around public health emergencies, collaboration and harmonization of medical device regulation, good regulatory practices and global convergence of standards (see page 173 for more information).

Registration for the pre-ICDRA conference event is open to delegates from medicines regulatory authorities and other interested parties such as industry, civil society, scientific institutions and non-governmental organizations. A registration fee is applicable to delegates other than medical products regulators. Registration for the 17th ICDRA is open exclusively to delegates from medicines regulatory authorities and is free of charge. The closing date for registrations is 31 August 2016. Early registration is encouraged.

► 17th ICDRA website, www.icdra.co.za